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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,360

Applicant(s)

WOLF, EUGENE M.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-25,27-43 and 50-69 is/are pending in the application.
- 4a) Of the above claim(s) 15,22,38,39 and 56-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-14, 16-21, 23-25, 27-37, 40-43, and 50-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment/Restriction

1. Newly submitted claims 56-69 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

- a. Claims 1, 3-14, 16-21, 23-25, 27-37, 40-43, and 50-55 (Invention I), are drawn to a subcombination (humeral head) and the method of using the subcombination, classified in class 23, subclass 19.14. Claims 15, 22, 38, 39, and 56-69 (Invention II), are drawn to a combination (humeral head and template punch) and the method of using the combination, classified in class 606, subclass 87 or subclass 99.
- b. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination requires a template punch and humeral head having a base extension including one or more fins, while the subcombination only requires a humeral head having a base extension including multiple fins. The subcombination has separate utility such as a humeral head that could be punched and/or glued to an exposed cut humeral surface. A guided saw could be used to prepare slots that will match the size and shape of each fin of the multiple fins.

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c. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15, 22, 38, 39, and 56-69 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-14, 16-21, 23-25, 27-37, 40-43, and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinnet (US 4,550,450 A; cited in Applicant's IDS) in view of Masini (US 5,571,203 A; cited in Applicant's IDS), Swanson et al. (US 4,042,980 A; cited in Applicant's IDS), and Chiron-Werke (DE 1164019; cited in Applicant's IDS).

As seen in Figures 1, 5, and 6, Kinnet discloses a total shoulder arthroplasty apparatus comprising a stemless humeral head (humeral component 10) for coupling to a cut humeral surface (see Figure 1). Said humeral head includes a base having a rotationally-stabilizing (see column 4, lines 40-42) base extension (fixation keel 21) protruding therefrom for impaction into a cancellous region of the cut humeral surface (see Figure 1; see entire document). Kinnett also

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discloses the claimed method of implanting the total shoulder arthroplasty apparatus (see columns 5-7). Although Kinnett shows the fixation keel 21 as having a slight depression (see Figure 1) and also that the fixation keel "provides increased mechanical advantages against torque and provides increased surface area of fixation" (see column 4, lines 40-42), he/she does not disclose the base extension as including a plurality of fins.

However, Masini teaches a prosthetic orthopedic device (see Figures 3-6) comprising a base extension including a plurality of fins (fins 310) in order to limit or prevent the rotational motion of the prosthetic orthopedic device relative to the anchor area/site (see column 4, lines 35-53). Masini also discloses that this plurality of fins (also referred to as anti-rotation means) "may be employed, or used in conjunction with a number of other bone-engaging orthopedic devices to prevent rotation" (see column 4, lines 51-53). Therefore, it would have been obvious to a person of ordinary skill in the art to have combined the teaching of a base extension including a plurality of fins, as taught by Masini, with the prosthetic orthopedic device of Kinnett, in order to limit or prevent the rotational motion of the prosthetic orthopedic device relative to the anchor area/site (i.e., cut humeral surface).

9.22.03
Kinnett does not disclose the fixation keel 21 as ^{being} ~~been~~ linear. However, Swanson et al. and Chiron-Werke teach at least one linear fin extending from the base of the prosthetic orthopedic device in order to anchor the prosthetic orthopedic device and prevent or limit rotational motion of it relative to the anchor area/site (see Swanson et al.'s column 3, lines 3-8; see Chiron-Werke entire document). Therefore, it would have been obvious to a person of ordinary skill in the art to have combined the teaching of at least one linear fin extending from the base of the prosthetic orthopedic device, as taught by Swanson et al. and Chiron-Werke, with the prosthetic orthopedic

device of Kinnett, in order to anchor the prosthetic orthopedic device and prevent or limit rotational motion of it relative to the anchor area/site (i.e., cut humeral surface).

Response to Arguments

4. Applicant's arguments filed June 30, 2003 have been fully considered but they are not persuasive. Applicant argues that the cited suggestion (column 4, lines 51-53) on Masini '203 "do not, however, provide the required suggestion to combine Kinnett and Masini". Further Applicant argues that "there is no reason why lines 51-53 should be read to suggest alternative orthopedic devices other than differently-^{configured}~~configured~~ hip replacement devices". Examiner respectfully disagrees.

First, Kinnett not only shows fixation keel 21 in the humeral component 10, but also shows a fixation keel 27 in the glenoid component 12. In other words, Kinnett discloses the subject matter of a fixation structure (i.e., keel, rib, fin, etc.) to "provide increased mechanical advantages against torque and provides increased surface area for fixation" (see column 4, lines 40-42). Second, although Masini '203 does not particularly refer to shoulder arthroplasty, he discloses (i) a bone-engaging orthopedic device having a base extension including one or more fins, (ii) the one or more fins may include other arrangements (i.e., curved fins, posts, and so forth), (iii) the one or more fins intended use as anti-rotation means (i.e., limit movement of the implant with respect to the bone-engaging surface and prevent rotation), and (iv) the one or more fins "may alternatively be employed, or used in conjunction with a number of other bone-engaging orthopedic devices to prevent rotation". The combination is deemed proper.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:00-4:30), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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A stylized handwritten signature consisting of two large, overlapping loops.

Javier G. Blanco
September 19, 2003

A handwritten signature in cursive script.

David H. Willse
Primary Examiner